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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,984	08/29/2003	Itzhak Bentwich	050992.0300.CPUS09	1983

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ROSETTA-GENOMICS
c/o PSWS
700 W. 47TH STREET
SUITE 1000
KANSAS CITY, MO 64112

EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,984	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006 and 25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-8, 11, 12 and 14 in the reply filed on September 13, 2006 is acknowledged. All pending claims have been canceled and new claims directed to a specific embodiment of the elected invention have been presented. Claims 21-40 are pending and examined on the merits.

Priority

No support could be found in application 60/457,788 for SEQ ID NO: 46759, 1916, 1917, 4641 or 4642. Therefore, the priority date accorded the disclosure of these sequences is August 29, 2003, the filing date of the instant application. If applicant believes the provisional application discloses the claimed sequences, the SEQ ID NOs designating these sequences in the provisional application should be pointed out in any response to this action.

Information Disclosure Statement

The information disclosure statement filed October 3, 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in

the English language. It has been placed in the application file, but the information referred to in reference B5 has not been considered.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: it is noted that the word "complementary" is misspelled as "complimentary" at numerous points in the specification.

The disclosure contains figures labeled 6A, 6B and 6C, however the brief description of the drawings contains no description of figure 6C.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-30 and 35-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 10, 13 and 14 of copending Application No. 10/535,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to SEQ ID NO: 46759, disclosed by the instant specification as a bioinformatically detectable gene. The claims of the '164 application are directed to

bioinformatically detectable gene sequences having the structural limitations of the instant claims. Therefore, the instant claims are a species of and would anticipate the generic claims of the '164 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-30 and 35-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8, 11 and 12 of copending Application No. 10/605,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to SEQ ID NO: 46759, disclosed by the instant specification as a bioinformatically detectable gene. The claims of the '838 application are directed to bioinformatically detectable gene sequences having the structural limitations of the instant claims. Therefore, the instant claims are a species of and would anticipate the generic claims of the '838 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Furthermore, the following serial numbers of co-pending applications contain claims in which an obviousness-type double patenting rejection might be applied or contain claims for which it cannot be determined if the claimed sequences conflict:

11/511,035 11/384,049 11/709,691 10/708,953 10/536,560 10/605,840 10/709,572 10/709,739 11/130,649 10/604,985 10/605,923 10/707,003 10/707,147 10707,975 10/708,204 10/708,951 10/708,952 11/418,870 10/604,726 10/604,926 10/604,943 10/604,945.

It is Applicants' burden to file appropriate terminal disclaimers for all relevant applications listed above. Furthermore, if Applicants are aware of any pending applications or patents, which are not listed above, it is Applicants' duty to disclose these applications or patents, and to submit an appropriate terminal disclaimer over these applications or patents as pertinent to the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 31-34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 31 and 32 depend from claims 29 and 30, respectively and recite that the nucleic acid of claim 29 or claim 30 is capable of modulating expression of a target gene. They fail to limit the parent claim because they do not further define the compound of claims 29 and 30, but merely states a particular function that would be expected, absent evidence to the

contrary, to be an inherent characteristic of the nucleic acids of claims 29 and 30.. Claims 33 and 34 are objected to due to their dependence from claims 31 and 32.

Claim 37 is objected to because of the following informalities: this claim is ungrammatical: the word "an" should be included before the first occurrence of the word "insert". Appropriate correction is required.

Applicant is advised that should claim 21 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Should claim 25 be found allowable, claim 38 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 37 is directed to a probe consisting of the nucleic acid of claim 21 and claim 38 is directed to a probe consisting of the sequence of claim 25. Because claims 37 and 38 do not recite any additional components, the subject matter of claims 37 and 38 is the same as claims 21 and 25.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 and 40 meet the three-pronged test for compliance with 112, sixth paragraph described in MPEP section 2181.

Claims 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 39 and 40 recite means plus function language in accordance with the provisions of 35 USC § 112, sixth paragraph, directed to a gene expression inhibition system comprising the vector of either claim 35 or claim 36 and a means for inserting said vector into a cell. Applicant points to paragraphs 24-26 of the specification as providing support for this claim. Paragraph 26 of the specification discloses that the invention includes a gene expression system including the vector and a "vector inserter, functional to insert the vector into a cell". Because the specification does not disclose any specific structures to define the means for inserting the vector into a cell, the metes and bounds of these claims cannot be determined.

While the prior art describes methods by which a vector can be transfected into cells, the specification does not disclose any specific structures to define the means for inserting the vector into a cell, nor does it provide a disclosure of what structures known

from the prior art will provide the function of inserting a vector into a cell. Therefore, this claim fails to meet the written description provision of 35 USC § 112, first paragraph.

Applicant may overcome these rejections by (A) clarifying the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element; or (B) stating on the record what structure, materials, or acts perform the function recited in the means-plus-function limitation, as described in MPEP 2181.

Claims 25-28, 30, 36, 38 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 depends from claim 21 and recites that the nucleic acid consists of SEQ ID NO: 46759, which is 761 nucleotides. Claim 25 is indefinite because claim 21 recites a nucleic acid consisting of 18-120 nucleotides in length. Because the maximum length of the claimed nucleic acid is 120 nucleotides, it is unknown how it could consist of the entirety of SEQ ID NO: 46759. Similarly, claim 28, which depends from claim 25 and recites a sequence with a maximum length of 24 nucleotides is indefinite because it recites the full length of SEQ ID NO: 46759. Claims 26, 27, 30, 36, 38 and 40 are indefinite for the same reason due to their dependence from claim 25.

Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 21 recites at limitation (a) a sequence comprising at least 18 consecutive nucleotides of SEQ ID NO: 46759. This sequence is defined at paragraphs 42969-70 as VGR3152 gene, which encodes VGR3152 precursor RNA. The specification at paragraph 18 defines precursor RNAs as being 50-120 nucleotides in length but does not provide support for precursor RNAs as short as 18 nucleotides. It is noted that paragraph 14 refers to RNAs 18-24 nucleotides in length, but this shorter RNA is disclosed as being produced from the 50-120 nucleotide precursor, it does not provide support for precursor RNAs shorter than 50 nucleotides in length. Claim 24, reciting the gene sequence of claim 21 that encodes a precursor RNA, is 18-24 nucleotides, contains new matter for the same reason.

Limitation (c) of claim 21, which also appears in claim 25, recites a sequence that is 34/58 identical to the nucleic acid of (a). In the remarks filed September 13, 2006, applicant points to table 1 as providing support for this limitation, stating that SEQ ID NO: 1916, which is encoded by SEQ ID NO: 46759, is 58 nucleotides in length and forms a hairpin secondary structure in which 34 nucleotides are paired. While this might provide explicit support for the numbers 34 and 58, this does not provide support for sequences defined by limitation (a), which can be as short as 18 nucleotides and requires only 18 nucleotides identical to SEQ ID NO: 46759. For the purposes of prior art, this limitation has been interpreted as the percent identity equivalent to 34/58:

58.6%. Similarly, the limitation in claims 33 and 34 of a nucleic acid 15/24 complementary to a binding sequence has been interpreted as requiring 62.5% complementarity.

In addition to any other new matter described above, claims 22-40 contain new matter due to their dependence from claim 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 24 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. (US 6,136,603).

Claim 21 is directed to a nucleic acid 18-120 nucleotides in length comprising 18 consecutive nucleotides of SEQ ID NO: 46759, a sequence 34/58 identical to the 18 consecutive nucleotides or the complement of either of these sequences. As described above in the new matter rejection, 34/58 is interpreted to mean a sequence having 58.6% identity with 18 consecutive nucleotides of the claimed sequence. Claim 24

limits claim 21, stating that the claimed nucleic acid is 18-24 nucleotides in length. Claim 37 is directed to a probe comprising the nucleic acid of claim 21.

Dean et al. disclose an antisense oligonucleotide, shown at column 7 as SEQ ID NO: 43, that comprises 20 nucleotides, 16 of which are complementary to nucleotides 582-597 of SEQ ID NO: 46759. The sequence disclosed by Dean et al. is 80% complementary to 18 consecutive nucleotides of SEQ ID NO: 46759, meeting limitation (c) of claim 21. As described in the claim objections above, the probe of claim 37 is interpreted as having a scope identical to that of claim 21.

Thus, Dean et al. disclose all limitations of and anticipate claims 21, 24 and 37.

Claims 21, 35, 37 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Homburger et al. (US 6,703,491).

Claim 21 is directed to a nucleic acid 18-120 nucleotides in length comprising 18 consecutive nucleotides of SEQ ID NO: 46759. Claim 35 is directed to a vector comprising the nucleic acid of claim 21 and claim 39 is directed to a gene expression inhibition system comprising the vector and a means for inserting the vector into a cell. Claim 37 is directed to a probe comprising the nucleic acid of claim 21.

Homburger et al. disclose a sequence, designated as SEQ ID NO: 25469, that is 61 nucleotides in length and shares 18 consecutive nucleotides with nucleotides 540-557 of SEQ ID NO: 46759. As described in the claim objections above, the probe of claim 37 is interpreted as having a scope identical to that of claim 21. At columns 12-14, Homburger et al. disclose that their invention includes nucleic acids and vectors

encoding any of SEQ ID NOs: 7-31,635. In section 5.2 beginning at column 24, Homburger et al. disclose vectors and host-vector expression systems for the nucleic acids of the invention. These systems are described as occurring in cells, indicating that a means for inserting vectors into cells such as those known in the art are utilized, meeting the limitations of claim 39.

Thus, Homburger et al. disclose all limitations of and anticipate claims 21, 35, 37 and 39.

Claims 21 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Okamoto et al. (US 6,849,431).

Claim 21 is directed to a nucleic acid 18-120 nucleotides in length comprising 18 consecutive nucleotides of SEQ ID NO: 46759. Claim 37 is directed to a probe comprising the nucleic acid of claim 21.

Okamoto et al. disclose a sequence, designated as SEQ ID NO: 12, that is 41 nucleotides in length and shares 18 consecutive nucleotides with nucleotides 536-553 of SEQ ID NO: 46759. As described in the claim objections above, the probe of claim 37 is interpreted as having a scope identical to that of claim 21.

Thus, Okamoto et al. disclose all limitations of and anticipate claims 21 and 37.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 24, 35, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. as applied to claims 21, 24 and 37 above, and further in view of Noonberg et al. (US 5,624,803).

Claims 21, 24 and 37 are described in the 102 rejection over Dean et al. Claims 35 and 39 recite a vector comprising the nucleic acid of claim 21 and a gene expression inhibition system that comprises the vector of claim 35 and a means for inserting the vector into a cell.

The teachings of Dean et al. are described in the 102 rejection over this reference. Dean et al. do teach vectors or a gene expression inhibition system comprising a vector.

Noonberg et al. teach *in vivo* oligonucleotide generators that are useful for producing antisense, ribozymes and triple helix molecules in cells for the purpose of gene regulation. At column 17, lines 2-13, Noonberg et al. teach the vectors of their invention can be administered to cells using techniques known in the art of gene therapy, including administration in liposomes or localized injection. This column provides a teaching of some means for inserting vectors into cells that are known in the art prior to the time of invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the antisense oligonucleotide taught by Dean et al. by

inserting it into the vectors and means for inserting vectors into cell taught by Noonberg et al. Noonberg et al. provide a motivation and reasonable expectation of success in using vectors to produce antisense oligonucleotides by teaching at column 7, lines 26-32 by teaching that such vectors produce oligonucleotides intracellularly in high yield and by actually making such vectors and demonstrating their successful use in producing oligonucleotides.

Thus, the invention of claims 21, 24, 35, 37 and 39 would have been obvious, as a whole, at the time of invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
November 9, 2006